

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-853 (GMS)
)	
AUROBINDO PHARMA LTD. and)	
AUROBINDO PHARMA USA, INC.,)	
)	
Defendants.)	

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-854 (GMS)
)	
MICRO LABS LIMITED and)	
MICRO LABS USA, INC.,)	
)	
Defendants.)	

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-855 (GMS)
)	
WATSON LABORATORIES, INC.,)	
ACTAVIS, INC. and)	
ACTAVIS PHARMA, INC.,)	
)	
Defendants.)	

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-880 (GMS)
)	
CIPLA LIMITED and CIPLA USA, INC.,)	
)	
Defendants.)	

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-881 (GMS)
)	
STRIDES PHARMA GLOBAL PTE)	
LIMITED and STRIDES PHARMA, INC.,)	
)	
Defendants.)	
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AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-882 (GMS)
)	
SUN PHARMACEUTICAL INDUSTRIES,)	
LTD., SUN PHARMA GLOBAL FZE and)	
SUN PHARMACEUTICAL INDUSTRIES,)	
INC.,)	
)	
Defendants.)	
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AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-899 (GMS)
)	
AJANTA PHARMA LIMITED and AJANTA)	
PHARMA USA INC.,)	
)	
Defendants.)	
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AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-900 (GMS)
)	
DR. REDDY'S LABORATORIES, LTD. and)	
DR. REDDY'S LABORATORIES, INC.,)	
)	
Defendants.)	
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AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-925 (GMS)
)	
AMNEAL PHARMACEUTICALS LLC and)	
AMNEAL PHARMACEUTICALS OF NEW)	
YORK, LLC,)	
)	
Defendants.)	
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AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-926 (GMS)
)	
APOTEX INC. and APOTEX CORP.,)	
)	
Defendants.)	
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AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-927 (GMS)
)	
BRECKENRIDGE PHARMACEUTICAL,)	
INC.,)	
)	
Defendant.)	
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AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-928 (GMS)
)	
HETERO USA INC., HETERO LABS LTD.)	
and HETERO LABS LTD. Unit V,)	
)	
Defendants.)	

JOINT STATUS REPORT

Pursuant to Federal Rule of Civil Procedure 16, District of Delaware Local Rule 16.2, and the Court's Orders Re: Case Management in Civil Cases (the "Order") and December 8, 2016 Stipulation to Extend Time, the parties, by and through their undersigned counsel, jointly submit this Status Report. Counsel for the parties participated in telephone conferences pursuant to the Order and as required by Federal Rule of Civil Procedure 26(f) on December 14, 2016. Fitzpatrick Cella Harper & Scinto and Morris Nichols Arsht & Tunnell LLP participated on behalf of Plaintiff Amgen Inc. ("Amgen" or "Plaintiff"); Leydig, Voit & Mayer, Ltd. and Morris James LLP participated on behalf of Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. ("Aurobindo"); Cozen O'Connor participated on behalf of Defendants Micro Labs Limited and Micro Labs USA, Inc. ("Micro Labs"); Haynes and Boone, LLP and Shaw Keller LLP participated on behalf of Defendants Watson Laboratories, Inc. and Actavis Pharma, Inc. ("Watson"); Kilpatrick Townsend & Stockton LLP and Phillips, Goldman, McLaughlin & Hall, P.A. participated on behalf of Defendants Cipla Limited and Cipla USA, Inc. ("Cipla"); Taft Stettinius & Hollister LLP participated on behalf of Defendants Strides Pharma Global PTE Limited and Strides Pharma, Inc. ("Strides"); Carlson Caspers and Phillips, Goldman, McLaughlin & Hall, P.A. participated on behalf of Defendants Sun Pharmaceutical Industries, Ltd., Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. ("Sun"); Schiff Hardin LLP and Phillips, Goldman, McLaughlin & Hall, P.A. participated on behalf of Defendants Ajanta Pharma Limited and Ajanta Pharma USA Inc. ("Ajanta"); Cozen O'Connor participated on behalf of Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's"); Robins Kaplan LLP and Potter Anderson & Corroon LLP participated on behalf of Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC ("Amneal"); Maddox Edwards, PLLC and Proctor Heyman Enerio LLP participated on behalf of Defendants

Apotex Inc. and Apotex Corp. (“Apotex”); Robert Vroom and Phillips, Goldman, McLaughlin & Hall, P.A. participated on behalf of Defendant Breckenridge Pharmaceutical, Inc.

(“Breckenridge”); and Cohen & Gresser LLP and Morris James LLP participated on behalf of Defendants Hetero USA Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit V (“Hetero”).

(Aurobindo, Micro Labs, Watson, Cipla, Strides, Sun, Ajanta, Dr. Reddy’s, Amneal, Apotex, Breckenridge, and Hetero are referred to collectively as “Defendants.”)

Attached for the Court’s consideration as Exhibit A is a chart summarizing the parties’ proposed schedule for this action. Attached for the Court’s consideration as Exhibit B is the parties’ proposed scheduling order. Attached for the Court’s consideration as Exhibit C are the case schedule deadlines the parties have agreed upon.

PLAINTIFF’S POSITION: As set forth in Section XII, Plaintiff believes these actions should be consolidated for all purposes, including discovery and trial of all issues.

DEFENDANTS’ POSITION: As set forth in Section XII, Defendants believe these actions should be coordinated for purposes of scheduling until trial, and all papers shall be filed in C.A. No. 1:16-cv-00853. Defendants believe a single consolidated trial related to Defendants’ invalidity counterclaims should take place. Defendants believe it is premature to decide whether separate trials related to Plaintiff’s infringement claims as against each Defendant should take place, and respectfully propose that this issue be decided at a later date.

I. Jurisdiction and Service

All Defendants have been served. The parties do not contest subject matter jurisdiction, personal jurisdiction, or venue solely for the limited purposes of this action only.

II. Substance of the Actions

These are Hatch-Waxman patent infringement actions relating to cinacalcet hydrochloride, which Amgen sells under the trademark Sensipar® in various dosage strengths (EQ 30 mg base,

EQ 60 mg base, and EQ 90 mg base) pursuant to approved New Drug Application No. 21-688. Sensipar® is approved to treat secondary hyperparathyroidism (“HPT”) in patients with chronic kidney disease on dialysis, hypercalcemia in patients with parathyroid carcinoma, and severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy. U.S. Patent No. 9,375,405 (the “’405 patent”) is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-688.

Aurobindo submitted Abbreviated New Drug Application (“ANDA”) No. 206125 seeking approval to market and sell generic cinacalcet hydrochloride tablets (“Aurobindo ANDA Product”) in the United States prior to the expiration of the ’405 patent. By letter dated August 5, 2016, Aurobindo notified Amgen that it had submitted its ANDA to the FDA.

Micro Labs submitted ANDA No. 206659 seeking approval to market and sell generic cinacalcet hydrochloride tablets (“Micro Labs ANDA Product”) in the United States prior to the expiration of the ’405 patent. By letter dated August 3, 2016, Micro Labs notified Amgen that it had submitted its ANDA to the FDA.

Watson submitted ANDA No. 204377 seeking approval to market and sell generic cinacalcet hydrochloride tablets (“Watson ANDA Product”) in the United States prior to the expiration of the ’405 patent. By letter dated August 10, 2016, Watson notified Amgen that it had submitted its ANDA to the FDA.

Cipla submitted ANDA No. 208915 seeking approval to market and sell generic cinacalcet hydrochloride tablets (“Cipla ANDA Product”) in the United States prior to the expiration of the ’405 patent. By letter dated August 16, 2016, Cipla notified Amgen that it had submitted its ANDA to the FDA.

Strides submitted ANDA No. 209226 seeking approval to market and sell generic cinacalcet hydrochloride tablets (“Strides ANDA Product”) in the United States prior to the expiration of the ’405 patent. By letter dated August 16, 2016, Strides notified Amgen that it had submitted its ANDA to the FDA.

Sun submitted ANDA No. 207008 seeking approval to market and sell generic cinacalcet hydrochloride tablets (“Sun ANDA Product”) in the United States prior to the expiration of the ’405 patent. By letter dated August 23, 2016, Sun notified Amgen that it had submitted its ANDA to the FDA.

Ajanta submitted ANDA No. 206797 seeking approval to market and sell generic cinacalcet hydrochloride tablets (“Ajanta ANDA Product”) in the United States prior to the expiration of the ’405 patent. By letter dated August 29, 2016, Ajanta notified Amgen that it had submitted its ANDA to the FDA.

Dr. Reddy’s submitted ANDA No. 208368 seeking approval to market and sell generic cinacalcet hydrochloride tablets (“Dr. Reddy’s ANDA Product”) in the United States prior to the expiration of the ’405 patent. By letter dated August 29, 2016, Dr. Reddy’s notified Amgen that it had submitted its ANDA to the FDA.

Amneal submitted ANDA No. 204364 seeking approval to market and sell generic cinacalcet hydrochloride tablets (“Amneal ANDA Product”) in the United States prior to the expiration of the ’405 patent. By letter dated September 20, 2016, Amneal notified Amgen that it had submitted its ANDA to the FDA.

Apotex submitted ANDA No. 209066 seeking approval to market and sell generic cinacalcet hydrochloride tablets (“Apotex ANDA Product”) in the United States prior to the

expiration of the '405 patent. By letter dated September 22, 2016, Apotex notified Amgen that it had submitted its ANDA to the FDA.

Breckenridge submitted ANDA No. 207006 seeking approval to market and sell generic cinacalcet hydrochloride tablets ("Breckenridge ANDA Product") in the United States prior to the expiration of the '405 patent. By letter dated September 28, 2016, Breckenridge notified Amgen that it had submitted its ANDA to the FDA.

Hetero submitted ANDA No. 209403 seeking approval to market and sell generic cinacalcet hydrochloride tablets ("Hetero ANDA Product") in the United States prior to the expiration of the '405 patent. By letter dated September 23, 2016, Hetero notified Amgen that it had submitted its ANDA to the FDA.

(The Aurobindo, Micro Labs, Watson, Cipla, Strides, Sun, Ajanta, Dr. Reddy's, Amneal, Apotex, Breckenridge, and Hetero ANDA Products are referred to collectively as "Defendants' ANDA Products.")

On September 22, 2016, Amgen filed Civil Action Nos. 16-853, 16-854, and 16-855 against Aurobindo, Micro Labs, and Watson, respectively. On September 29, 2016, Amgen filed Civil Action Nos. 16-880, 16-881, and 16-882 against Cipla, Strides, and Sun, respectively. On October 5, 2016, Amgen filed Civil Action Nos. 16-889 and 16-900 against Ajanta and Dr. Reddy's, respectively. On October 11, 2016, Amgen filed Civil Action Nos. 16-925, 16-926, 16-927, and 16-928 against Amneal, Apotex, Breckenridge, and Hetero, respectively. In each of these actions, Amgen alleges that the submission of Defendants' ANDAs were acts of infringement of the '405 patent under 35 U.S.C. § 271(e)(2) and that the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA products in the United States

would infringe one or more claims of the '405 patent, directly or indirectly, under 35 U.S.C. § 271 (a), (b), and/or (c).

Amgen also owns U.S. Patent No. 6,011,068, which is listed in the Orange Book listing for Sensipar® and expires on March 8, 2018. Defendants have not challenged that patent.

Defendants have alleged in answers, defenses, and counterclaims that the claims of the '405 patent are invalid and/or would not be infringed by the commercial manufacture, use, sale, offer to sell, or importation of the Defendants' ANDA Products.

III. Identification of Issues

1. Whether Defendants' submission of their respective ANDAs was an act of infringement of the '405 patent and whether the manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Products would infringe the '405 patent either directly or indirectly.

2. Whether any of the asserted claims of the '405 patent are invalid.

3. Whether any party is entitled to an award of attorneys' fees, costs, and/or expenses under 35 U.S.C. § 285.

IV. Narrowing of Issues

The parties expect that, as discovery proceeds and the cases progress, they may be able to narrow the issues by way of stipulation or agreement.

PLAINTIFF'S POSITION: Plaintiff believes there should be no summary judgment motions in these actions.

DEFENDANTS' POSITION: Pursuant to the Court's standard practice concerning dispositive motion practice, each Defendant would like the opportunity to seek leave to file motion(s) for summary judgment of non-infringement following Plaintiff's service of its infringement contentions. Additionally, one or more Defendants would like the opportunity to

seek leave to file motion(s) for summary judgment of invalidity within the time allowed in the Scheduling Order.

V. Relief¹

A. Plaintiff seeks at least the following relief:

1. A Judgment that the asserted claims of the '405 patent are not invalid, are not unenforceable, and are infringed by Defendants' submission of their respective ANDAs, and that Defendants' making, using, offering to sell, or selling in the United States, or importing into the United States Defendants' ANDA Products will infringe the asserted claims of the '405 patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Defendants' ANDAs shall be a date which is not earlier than the expiration date of the '405 patent, including any extensions and/or additional periods of exclusivity to which Amgen is or becomes entitled.

3. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Defendants' ANDA Products until after the expiration of the '405 patent, including any extensions and/or additional periods of exclusivity to which Amgen is or becomes entitled.

4. Such other and further relief deemed proper by the Court, including attorneys' fees, costs, and expenses under 35 U.S.C. § 285, and further including damages should Defendants commercially make, use, offer to sell, or sell within the United States, or import into

¹ A party's submission of this joint report should not be considered an admission that any other party is entitled to seek the relief listed in this section.

the United States, Defendants' ANDA Products prior to the expiration of the '405 patent, including any extensions or exclusivities.

B. Defendants seek at least the following relief:

1. A judgment declaring the asserted claims of the '405 patent invalid.
2. A judgment that no asserted claim of the '405 patent is infringed.
3. Dismissal of the complaints with prejudice.
4. Such other and further relief as the Court may deem just and proper,

including the award of attorneys' fees and expenses of litigation as an exceptional case under 35 U.S.C. §285.

VI. Amendment of Pleadings

The parties propose a **June 30, 2017** deadline for amendment of pleadings.

VII. Joinder of Parties

The parties propose a **June 30, 2017** deadline to add any additional parties.

VIII. Discovery

A. Types of Discovery

The parties met and conferred pursuant to Rule 26(f) (Fed. R. Civ. P. 26(f)) on December 14, 2016 to discuss case management and a discovery plan. The parties currently contemplate taking fact and expert discovery regarding the issues identified above in Paragraph 3, as outlined in the parties' Joint Proposed Scheduling Order attached as Exhibit B.

One or more of the parties request, at a minimum, the following types of discovery: (i) written discovery and the discovery and production of documents relating to facts and the parties' contentions; (ii) fact depositions, including testimony pursuant to Federal Rule of Civil Procedure

30(b)(6); (iii) the production of samples of Defendants' ANDA products; and (iv) expert discovery (including expert reports and depositions) on issues related to validity and infringement.

PLAINTIFF'S POSITION: Plaintiff believes Defendants should be required to produce samples of API and excipients used to make Defendants' ANDA products. The API and excipients will be used to make Defendants' ANDA products, which would, if the ANDAs were approved, be made, used, sold, offered for sale, and/or imported into the United States. Plaintiff believes testing of the API, excipients and finished ANDA products is necessary.

DEFENDANTS' POSITION: Defendants do not believe that the production of samples of their ANDA products, API or excipients are necessary or appropriate under the circumstances of this case, particularly at an early stage of discovery, as Amgen has proposed. Defendants believe that all infringement issues may be resolved by the specifications for their ANDA products, rather than through testing of samples of ANDA products, API or excipients.

B. *Limitations on Discovery*

The parties agree that the default limitations on discovery set forth in the Federal Rules of Civil Procedure and in the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("Default Standard for Discovery") shall apply to this action, subject to the parties reaching a future agreement, in writing, modifying those limitations, or the Court entering an order modifying those limitations for good cause shown, except that:

1. Requests for Admission under Federal Rule of Civil Procedure 36

The parties agree that Plaintiff may serve a maximum of 30 requests for admission on each Defendant, and that each Defendant may serve a maximum of 30 requests for admission on Plaintiff. The parties further agree that, for purpose of calculating the number of requests for admission allowed, the parent company and its subsidiaries or affiliates shall count as one

Defendant. The parties will meet and confer concerning authenticity of documents without the need for formal requests for admission.

2. Interrogatories

Plaintiffs may serve a maximum of 10 interrogatories which shall be identical on all the Defendants, and in addition, a maximum of 5 interrogatories which may be unique on each Defendant. Defendants may collectively serve a maximum 10 interrogatories on Plaintiff, and in addition, each Defendant may serve a maximum of 5 individual interrogatories on Plaintiff. For purpose of calculating the number of interrogatories allowed, the parent company and its subsidiaries or affiliates shall count as one Defendant.

3. Fact Depositions

PLAINTIFF'S POSITION: If the cases are consolidated, Plaintiff may take seven (7) fact depositions of each defendant and a maximum of five (5) additional fact depositions which may be of non-party witnesses. Each deposition shall be a maximum of 7 hours unless extended by agreement of the parties or leave of the Court. If the cases are not consolidated, then the Federal Rules of Civil Procedure will govern the number of depositions that may be taken.

DEFENDANTS' POSITION: Plaintiff may take three (3) fact depositions of each Defendant and a maximum of four (4) additional fact depositions of non-party witnesses or Defendants, but no more than one of these four additional depositions may be taken of any one Defendant. Each deposition shall be a maximum of 7 hours unless extended by agreement of the parties or leave of the Court, except that depositions of inventors on the '405 patent may be 14 hours (but each inventor deposition shall count as one deposition).

The parties agree the defendants may take a maximum of twenty (20) fact depositions, including of third parties. In the absence of agreement, each defendant shall have the right to notice at least one deposition of its choice. If an interpreter is necessary for any deposition, the

time limit allotted under the Federal Rules is doubled to fourteen (14) hours. Every 7 hours of Rule 30(b)(6) deposition testimony counts as one deposition. For purpose of calculating the number of depositions allowed, the parent company and its subsidiaries or affiliates shall count as one defendant.

4. Other

The parties will seek to reach additional agreements regarding electronic discovery to minimize the burden and expense of such discovery on all parties.

C. *Protective Order*

The parties agree that a protective order is necessary to protect the confidential information that will be exchanged in connection with this action, and will submit a proposed Protective Order for the Court's consideration.

IX. Estimated Trial Length

PLAINTIFF'S POSITION: Amgen believes that ten (10) days will be required to resolve the issues set forth in the parties' respective pleadings.

DEFENDANTS' POSITION: Defendants believe that seven (7) days will be required to resolve the issues set forth in the parties' respective pleadings.

The parties will cooperate in an attempt to reduce the length of trial through the use of stipulations and other means for expediting the presentation of evidence.

X. Jury Trial

The parties agree that because no money damages are currently being sought, there is no present need for a jury trial.

XI. Settlement

The parties are open to referral to a Magistrate Judge for informal mediation or settlement discussions at an appropriate time, but the parties have not yet determined whether mediation is likely to be successful.

XII. Other Matters Conducive To Just, Speedy, And Inexpensive Determination Of This Action

PLAINTIFF'S POSITION: Amgen believes these actions should be consolidated for all purposes, including discovery and trial of all issues.

DEFENDANTS' POSITION: Defendants believe these actions should be coordinated for purposes of scheduling until trial, and all papers shall be filed in C.A. No. 1:16-cv-00853. Defendants believe a single consolidated trial related to Defendants' invalidity counterclaims should take place. Defendants believe it is premature to decide whether separate trials related to Plaintiff's infringement claims as against each Defendant should take place, and respectfully propose that this issue be decided at a later date.

XIII. Conference of Counsel

Counsel for the parties conferred about each of the above matters on and after December 14, 2016. Should the Court have any questions regarding the information set forth above, counsel for all parties are prepared to provide any additional information requested by the Court.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Amgen Inc.

PHILLIPS, GOLDMAN, McLAUGHLIN & HALL, P.A.

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

*Attorneys for Defendants Cipla Limited,
Cipla USA, Inc. Ajanta Pharma Limited,
Ajanta Pharma USA Inc., Breckenridge
Pharmaceutical, Inc., Sun Pharmaceutical
Industries, Ltd., Sun Pharma Global FZE and
Sun Pharmaceutical Industries, Inc.*

MORRIS JAMES LLP

/s/ Mary B. Matterer

Richard K. Herrmann (#405)
Mary B. Matterer (#2696)
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
rherrmann@morrisjames.com
mmatterer@morrisjames.com
(302) 888-6800

*Attorneys for Defendants Aurobindo Pharma
Ltd. and Aurobindo Pharma USA, Inc.*

SEITZ, VANOGTROP & GREEN, PA

/s/ Jared T. Green

James S. Green, Sr. (#481)
Jared T. Green (#5179)
222 Delaware Avenue, Suite 500
P.O. Box 68
Wilmington, DE 19899
(302) 888-0600
jgreen@svglaw.com
jtgreen@svglaw.com

*Attorneys for Defendants Strides Pharma
Global PTE Limited and Strides Pharma, Inc.*

POTTER ANDERSON & CORROON LLP

/s/ David E. Moore

David E. Moore (#3983)
Bindu A. Palapura (#5370)
Stephanie E. O'Byrne (#4446)
Hercules Plaza, 6th Floor
1313 North Market Street
Wilmington, DE 19801
(302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
sobyrne@potteranderson.com

*Attorneys for Defendants Amneal
Pharmaceuticals LLC and Amneal
Pharmaceuticals of New York, LLC*

MORRIS JAMES LLP

/s/ Kenneth L. Dorsney

Kenneth L. Dorsney (#3726)
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
kdorsney@morrisjames.com
(302) 888-6800

*Attorneys for Defendants Hetero USA Inc.,
Hetero Labs Ltd. and Hetero Labs Ltd. Unit V*

PROCTOR HEYMAN ENERIO LLP

/s/ Dominick T. Gattuso

Dominick T. Gattuso (#3630)
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@proctorheyman.com

*Attorneys for Defendants Apotex Inc. and
Apotex Corp.*

COZEN O'CONNOR

/s/ Joseph J. Bellew

Joseph J. Bellew (#4816)
1201 North Market Street, Suite 1001
Wilmington, DE 19801
(302) 295-2025
jbellew@cozen.com

*Attorneys for Defendants Micro Labs Limited,
Micro Labs USA, Inc., Dr. Reddy's
Laboratories, Ltd. and Dr. Reddy's
Laboratories, Inc.*

SHAW KELLER LLP

/s/ Karen E. Keller

John W. Shaw (#3362)
Karen E. Keller (#4489)
David M. Fry (#5486)
300 Delaware Avenue, Suite 1120
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
dfry@shawkeller.com

*Attorneys for Defendants Watson Laboratories,
Inc. and Actavis Pharma, Inc.*

December 15, 2016

EXHIBIT A – PROPOSED CASE SCHEDULE

Event	Deadline
FACT DISCOVERY	
Initial Disclosures	January 6, 2017
Delaware Default Standard ¶ 3 Disclosures	January 6, 2017
Delaware Default Standard ¶ 4(a) Disclosure	January 6, 2017
Delaware Default Standard ¶ 4(b) Disclosure Defendants produce ANDAs	January 20, 2017
Production of samples of the accused ANDA products and the excipients and API used to make the ANDA products	Plaintiff's Proposal: January 20, 2017 Defendants' Proposal: ANDA products, API and excipients need not be produced
Delaware Default Standard ¶ 4(c) Disclosure	February 10, 2017
Delaware Default Standard ¶ 4(d) Disclosure	March 3, 2017
Document Production Substantially Complete	May 3, 2017
Deadline to Amend the Pleadings	June 30, 2017
Deadline to Join Additional Parties	June 30, 2017
Completion of Fact Discovery	July 14, 2017
SUMMARY JUDGMENT	
Deadline for Letter Briefs Seeking Leave to File Summary Judgment Motions	Plaintiff's Proposal: No summary judgment motions Defendants' Proposal: February 24, 2017
Deadline for Answering Letter Briefs	Plaintiff's Proposal: No summary judgment motions Defendants' Proposal: March 3, 2017
Deadline for Reply Letter Briefs	Plaintiff's Proposal: No summary judgment motions Defendants' Proposal: March 8, 2017

Event	Deadline
CLAIM CONSTRUCTION	
Parties shall exchange a list of proposed terms for construction	February 24, 2017
Parties shall exchange proposed constructions	March 10, 2017
Parties shall submit a Final Joint Claim Chart	March 17, 2017
Opening claim construction briefs	March 24, 2017
Answering claim construction briefs	April 14, 2017
Plaintiff shall submit Joint Appendix of Intrinsic Evidence	April 14, 2017
Markman Hearing	May 2017 proposed; at the Court's convenience
EXPERT DISCOVERY	
Opening expert reports on which a party bears the burden of proof	August 11, 2017
Rebuttal expert reports	September 8, 2017
Reply expert reports	September 29, 2017
Completion of expert discovery	November 3, 2017
TRIAL PHASE	
Plaintiff Provides Draft Joint Pretrial Order to Defendants	30 days prior to Pretrial Conference (December 2017)
Defendants Provide Response to Plaintiff's Draft Pretrial Order	20 days prior to Pretrial Conference (December 2017)
Submission of Joint Proposed Pretrial Order	One week prior to Pretrial Conference
Pretrial Conference	January 2018 proposed; at the Court's convenience
Trial Begins	January 2018 proposed; date to be determined by the Court

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-853 (GMS)
)	
AUROBINDO PHARMA LTD. and)	
AUROBINDO PHARMA USA, INC.,)	
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Defendants.)	

AMGEN INC.,)	
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MICRO LABS LIMITED and MICRO LABS)	
USA, INC.,)	
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Defendants.)	

AMGEN INC.,)	
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AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-900 (GMS)
)	
DR. REDDY'S LABORATORIES, LTD. and)	
DR. REDDY'S LABORATORIES, INC.,)	
)	
Defendants.)	

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-925 (GMS)
)	
AMNEAL PHARMACEUTICALS LLC and)	
AMNEAL PHARMACEUTICALS OF NEW)	
YORK, LLC,)	
)	
Defendants.)	

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-926 (GMS)
)	
APOTEX INC. and APOTEX CORP.,)	
)	
Defendants.)	

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-927 (GMS)
)	
BRECKENRIDGE PHARMACEUTICAL,)	
INC.,)	
)	
Defendant.)	

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 16-928 (GMS)
)	
HETERO USA INC., HETERO LABS LTD.)	
and HETERO LABS LTD. Unit V,)	
)	
Defendants.)	

[PROPOSED] SCHEDULING ORDER

This _____ day of _____, 20____, the Court having conducted a Rule 16 Scheduling Conference pursuant to Local Rule 16.2(b) on _____, and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation or binding arbitration;

IT IS ORDERED that:

1. **Rule 26(a) Initial Disclosures.** Unless otherwise agreed to by the parties, they shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a) on or before January 6, 2017.
2. **Joinder of other Parties and Amendment of Pleadings.** All motions to join other parties and amend the pleadings shall be filed on or before June 30, 2017.
3. **Reliance Upon Advice of Counsel.** Plaintiff has not asserted willfulness.
4. **Markman Claim Construction Hearing.** A *Markman* claim construction hearing shall be held on May _____, 2017 at _____.m. The *Markman* hearing is scheduled for a total of 3 hours with each side having 1.5 hours. The parties shall meet and confer regarding narrowing and reducing the number of claim construction issues. On or before March 17, 2017 the parties shall submit a Final Joint Claim Chart which shall include citations to intrinsic evidence. The Plaintiff shall submit to the Court, a Joint Appendix of Intrinsic Evidence (the “Joint

Appendix”) containing all intrinsic evidence relied upon in the claim construction briefing. A sample table of contents of the Joint Appendix can be located on this Court’s website at www.ded.uscourts.gov. The Joint Appendix shall be filed on the same day as the answering claim construction briefs. The parties shall file opening claim construction briefs on March 24, 2017, and answering claim construction briefs on April 14, 2017. Briefing will be presented pursuant to the Court’s Local Rules.

5. **Discovery.** All fact discovery in this case shall be initiated so that it will be completed on or before July 14, 2017. Opening expert reports on issues on which a party bears the burden of proof shall be served on or before August 11, 2017. Rebuttal expert reports shall be served on or before September 8, 2017. Reply expert reports shall be served on or before September 29, 2017. Expert Discovery in this case shall be initiated so that it will be completed on or before November 3, 2017.

a. **Discovery and Scheduling Matters:** Should counsel find they are unable to resolve a discovery¹ or scheduling matter, the party seeking the relief shall contact chambers at (302) 573-6470 to schedule a telephone conference. Not less than forty-eight hours prior to the teleconference, the parties shall file with the Court, via electronic means (CM/ECF), a **joint, non-argumentative** letter agenda not to exceed two (2) pages outlining the issue(s) in dispute. A sample letter can be located on this Court’s website at www.ded.uscourts.gov. After the parties have had three (3) discovery teleconferences, they will be required to file a joint letter showing good cause why the Court should permit a fourth discovery teleconference. Should the Court find further briefing necessary upon conclusion of the telephone conference, unless otherwise directed,

¹ Unless the Court otherwise orders, should counsel be unable to agree on the discovery of paper and electronic documents, the Court’s “Default Standard for Discovery, Including Discovery of Electronically Stored Information” (“ESI”) shall govern

the party seeking relief shall file with the Court a **TWO PAGE LETTER**, exclusive of exhibits, describing the issues in contention. The responding party shall file within five (5) days from the date of service of the opening letter an answering letter of no more than **TWO PAGES**. The party seeking relief may then file a reply letter of no more than **TWO PAGES** within three (3) days from the date of service of the answering letter.

6. **Confidential Information and Papers filed under Seal.** Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, they should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court within ten (10) days from the date of this order. When filing papers under seal, counsel should deliver to the Clerk an original and two copies of the papers.

If after making a diligent effort the parties are unable to agree on the contents of the joint proposed protective order, then they shall follow the dispute resolution process outlined in paragraph 5(a).

7. **Settlement Conference.** Pursuant to 28 U.S.C. §636, this matter is referred to the United States Magistrate Judge for the purpose of exploring the possibility of a settlement. If the parties agree that the possibility of settlement may be enhanced by such referral, the parties shall contact the assigned United States Magistrate Judge to schedule a settlement conference with counsel and the clients.

8. **Summary Judgment Motions. [Plaintiff's Proposal:** There shall be no summary judgement motions in these actions.] **[Defendants' Proposal:** Prior to filing any summary judgment motion, the parties must submit letter briefs seeking permission to file the motion. The opening letter brief shall be no longer than five (5) pages and shall be filed with the Court no later

than February 24, 2017. Answering letter briefs shall be no longer than five (5) pages and filed with the court no later than March 3, 2017. Reply letter briefs shall be no longer than three (3) pages and filed with the Court on or before March 8, 2017. If the Court determines that argument is necessary to assist in the resolution of any request to file summary judgment, it shall notify the parties of the date and time on which the Court will conduct a telephone conference to hear such argument. **Unless the Court directs otherwise, no letter requests to file a motion for summary judgment may be filed at a time before the dates set forth in paragraph 8.]**

9. **Case Dispositive Motions: [Plaintiff's Proposal:** There shall be no case dispositive motions in these actions.] **[Defendants' Proposal:** To the extent permitted, all case or issue dispositive motions shall be served and filed within two weeks of the Court's decision to permit the filing of such motions. Briefing will be presented pursuant to the Court's Local Rules. The parties may agree on an alternative briefing schedule. Any such agreement shall be in writing and filed with the Court for the Court's approval. Any request for extensions of time as set forth in this Scheduling Order **must** be accompanied by an explanation or your request will be denied.

10. **Applications by Motion.** Except as provided in this Scheduling Order or for matters relating to scheduling, any application to the Court shall be by written motion filed, via electronic means (CM/ECF). Unless otherwise requested by the Court, counsel shall **not** deliver copies of papers or correspondence to Chambers. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

11. **Oral Argument.** If the Court believes that oral argument is necessary, the Court will schedule a hearing Pursuant to District of Delaware Local Rule 7.1.4.

12. **Pretrial Conference.** On _____, beginning at _____.m., the Court will hold a Pretrial Conference, in Chambers for Jury trials and via telephone for Bench trials, with counsel. Unless otherwise ordered by the Court, the parties should assume that filing the Joint Pretrial Order satisfies the pretrial disclosure requirement in Federal Rule of Civil Procedure 26(a)(3). A sample form of Pretrial Order can be located on this court's website at www.ded.uscourts.gov. Thirty (30) days before the Joint Proposed Pretrial Order is due, Plaintiff's counsel shall forward to Defendants' counsel a draft of the pretrial order containing the information Plaintiff proposes to include in the draft. Defendants' counsel shall, in turn, provide to Plaintiff's counsel any comments on the Plaintiff's draft, as well as the information Defendants propose to include in the proposed pretrial order. .

13. **Motions *in limine*²: NO MOTIONS IN LIMINE SHALL BE FILED;** instead, the parties shall be prepared to address their evidentiary issues at the Pretrial Conference and during trial (before and after the trial day). The parties shall file with the Court the **joint** Proposed Final Pretrial Order in accordance with the terms and with the information required by the form of Final Pretrial Order, which can be located on this Court's website at www.ded.uscourts.gov, one week prior to the Pretrial Conference.

14. **Trial.** These matters are scheduled for a _____ day bench trial beginning at 9:30 a.m. on January _____, 2018.

15. **Scheduling.** The parties shall contact chambers, at (302) 573-6470, only in situations where scheduling relief is sought, and only then when ALL participating counsel is on the line for purposes of selecting a new date.

² The parties should simply list, in an Exhibit to be attached to the Pretrial order, the issues under a heading such as "Plaintiff's [name of party] List of Evidentiary Issues It Intends To Raise.

16. **Consolidation.** The interests of judicial economy and efficiency are best served through a [**Plaintiff's Proposal:** consolidation] [**Defendants' Proposal:** coordination]. of *Amgen Inc. v. Aurobindo Pharma Limited et al.*, C.A. No. 1:16-cv-00853; *Amgen Inc. v. Micro Labs Limited et al.*, C.A. No. 1:16-cv-00854; *Amgen Inc. v. Watson Laboratories, Inc. et al.*, C.A. No. 1:16-cv-00855; *Amgen Inc. v. Cipla Limited et al.*, C.A. No. 1:16-cv-00880; *Amgen Inc. v. Strides Pharma Global PTE Limited et al.*, C.A. No. 1:16-cv-00881; *Amgen Inc. v. Sun Pharmaceutical Industries, Ltd. et al.*, C.A. No. 1:16-cv-00882; *Amgen Inc. v. Ajanta Pharma Limited et al.*, C.A. No. 1:16-cv-00899; *Amgen Inc. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 1:16-cv-00900; *Amgen Inc. v. Amneal Pharmaceuticals LLC et al.*, C.A. No. 1:16-cv-00925; *Amgen Inc. v. Apotex Inc., et al.*, C.A. No. 1:16-cv-000926; *Amgen Inc. v. Breckenridge Pharmaceutical, Inc.*, C.A. No. 1:16-cv-00927; and *Amgen Inc. v. Hetero USA Inc. et al.*, C.A. No. 1:16-cv-00928 for [**Plaintiff's Proposal:** all purposes] [**Defendants' Proposal:** pretrial purposes]. The lead case in which all pretrial pleadings shall be filed is C.A. No. 1:16-cv-00853. A [**Plaintiff's Proposal:** consolidated] [**Defendants' Proposal:** coordinated]. consolidated case caption shall be used for all such pretrial filings.

UNITED STATES DISTRICT JUDGE

EXHIBIT C

Event	Deadline
FACT DISCOVERY	
Initial Disclosures	January 6, 2017
Delaware Default Standard ¶ 3 Disclosures	January 6, 2017
Delaware Default Standard ¶ 4(a) Disclosure	January 6, 2017
Delaware Default Standard ¶ 4(b) Disclosure Defendants produce ANDAs	January 20, 2017
Delaware Default Standard ¶ 4(c) Disclosure	February 10, 2017
Delaware Default Standard ¶ 4(d) Disclosure	March 3, 2017
Document Production Substantially Complete	May 3, 2017
Deadline to Amend the Pleadings	June 30, 2017
Deadline to Join Additional Parties	June 30, 2017
Completion of Fact Discovery	July 14, 2017
CLAIM CONSTRUCTION	
Parties shall exchange a list of proposed terms for construction	February 24, 2017
Parties shall exchange proposed constructions	March 10, 2017
Parties shall submit a Final Joint Claim Chart	March 17, 2017
Opening claim construction briefs	March 24, 2017
Answering claim construction briefs	April 14, 2017
Plaintiff shall submit Joint Appendix of Intrinsic Evidence	April 14, 2017
Markman Hearing	May 2017 proposed; at the Court's convenience

Event	Deadline
EXPERT DISCOVERY	
Opening expert reports on which a party bears the burden of proof	August 11, 2017
Rebuttal expert reports	September 8, 2017
Reply expert reports	September 29, 2017
Completion of expert discovery	November 3, 2017
TRIAL PHASE	
Plaintiff Provides Draft Joint Pretrial Order to Defendants	30 days prior to Pretrial Conference (December 2017)
Defendants Provide Response to Plaintiff's Draft Pretrial Order	20 days prior to Pretrial Conference (December 2017)
Submission of Joint Proposed Pretrial Order	One week prior to Pretrial Conference
Pretrial Conference	January 2018 proposed; at the Court's convenience
Trial Begins	January 2018 proposed; date to be determined by the Court